

Food and Drug Administration, HHS

§ 890.5110

regarding general requirements concerning records, and § 820.198, regarding complaint files.

[61 FR 8439, Mar. 4, 1996, as amended at 66 FR 38817, July 25, 2001]

§ 890.3920 Wheelchair component.

(a) *Identification.* A wheelchair component is a device intended for medical purposes that is generally sold as an integral part of a wheelchair, but may also be sold separately as a replacement part. Examples of wheelchair components are the following: Armrest, narrowing attachment, belt, extension brake, curb climber, cushion, antitip device, footrest, handrim, hill holder, leg rest, heel loops, and toe loops.

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 890.9.

[48 FR 53047, Nov. 23, 1983, as amended at 59 FR 63014, Dec. 7, 1994; 66 FR 38817, July 25, 2001]

§ 890.3930 Wheelchair elevator.

(a) *Identification.* A wheelchair elevator is a motorized lift device intended for medical purposes to provide a means for a disabled person to move a wheelchair from one level to another.

(b) *Classification.* Class II (performance standards).

§ 890.3940 Wheelchair platform scale.

(a) *Identification.* A wheelchair platform scale is a device with a base designed to accommodate a wheelchair. It is intended for medical purposes to weigh a person who is confined to a wheelchair.

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 890.9. The device is also exempt from the current good manufacturing practice regulations in part 820 of this chapter, with the exception of § 820.180, regarding general requirements concerning

records and § 820.198, regarding complaint files.

[48 FR 53047, Nov. 23, 1983, as amended at 59 FR 63015, Dec. 7, 1994; 66 FR 38817, July 25, 2001]

Subpart E [Reserved]

Subpart F—Physical Medicine Therapeutic Devices

§ 890.5050 Daily activity assist device.

(a) *Identification.* A daily activity assist device is a modified adaptor or utensil (e.g., a dressing, grooming, recreational activity, transfer, eating, or homemaking aid) that is intended for medical purposes to assist a patient to perform a specific function.

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 890.9. If the device is not labeled or otherwise represented as sterile, the device is also exempt from the current good manufacturing practice regulations in part 820 of this chapter, with the exception of § 820.180, regarding general requirements concerning records and § 820.198, regarding complaint files.

[48 FR 53047, Nov. 23, 1983, as amended at 66 FR 38817, July 25, 2001]

§ 890.5100 Immersion hydrobath.

(a) *Identification.* An immersion hydrobath is a device intended for medical purposes that consists of water agitators and that may include a tub to be filled with water. The water temperature may be measured by a gauge. It is used in hydrotherapy to relieve pain and itching and as an aid in the healing process of inflamed and traumatized tissue, and it serves as a setting for removal of contaminated tissue.

(b) *Classification.* Class II (performance standards).

§ 890.5110 Paraffin bath.

(a) *Identification.* A paraffin bath is a device intended for medical purposes that consists of a tub to be filled with liquid paraffin (wax) and maintained at an elevated temperature in which the